

**REMARKS**

Claims 11-20 were pending in the present application. Claims 14-16 have been withdrawn from consideration. Claims 12 and 13 have been canceled without prejudice to their presentation in another application. Claims 11, 17, and 20 have been amended, support for which can be found throughout the specification and claims. No new matter has been added. Upon entry of the present amendment, claims 11 and 14-20 will be pending (of which 14-16 are withdrawn).

**I. The Claimed Invention Is Novel****A. The Imura and Terashita References**

Claims 11-13 and 17-20 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent Application Publication No. US 2003/0187038 (hereinafter, the “Imura reference”) and by U.S. Patent Application Publication No. US 2006/0069133 (hereinafter, the “Terashita reference”). Applicants traverse the rejection and respectfully request reconsideration, in view of the amended claims, because the Imura and Terashita references do not teach every feature recited in the amended claims.

The Imura reference, for example, reports the following specific compounds having angiotensin II antagonistic activity in paragraph [0028]: losartan, eprosartan, candesartan cilexetil, candesartan, valsartan, temisartan, irbesartan, olmesartan, and tasosartan. Applicants have amended claim 11 by incorporating features of claim 12. Applicants are not able to locate any portion of either the Imura reference or the Terashita reference that specifically teach the compounds recited in amended claim 11.

Thus, the Imura and Terashita references do not teach every feature recited in the rejected claims. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §102(e) be withdrawn.

**II. The Claimed Invention Is Sufficiently Enabled**

Claims 11-13 and 17-20 are rejected under 35 U.S.C. §112, first paragraph as allegedly failing to provide an enabling disclosure. Although the Office recognizes that the claims are enabled for treating metabolic syndrome, the Office asserts that it would require undue

experimentation regarding “prevention” of metabolic syndrome. Although Applicants disagree with the reasoning set forth in the Office Action, solely to advance prosecution of the present application, claim 11 has been amended to delete the phrases “and/or prevention” and “or prevention.” Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph be withdrawn.

### **III. The Claimed Invention Is Supported by Ample Written Description**

Claims 11-13 and 17-20 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Office asserts that the phrase “a metabolically neutral antihypertensive substance” lacks sufficient written description support in the specification broad enough to support the genus. The Office further asserts that the phrase “a metabolically neutral antihypertensive substance” is supported by reference to calcium antagonist compounds. Although Applicants disagree with the conclusions regarding a lack of written description set forth in the Office Action, solely to advance prosecution of the present application, claim 11 has been amended to delete the phrase “a metabolically neutral antihypertensive substance” and replace therewith “a calcium antagonist compound.” Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph be withdrawn.

### **IV. The Claims Are Clear And Definite**

Claims 11-13 and 17-20 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. The Office appears to assert that the term “alone” in claim 11 is ambiguous because it allegedly may be construed two different ways. Applicants traverse the rejection and respectfully request reconsideration because the claims are clear and definite.

For the sake of convenience, Applicants present claim 11 below.

11. (previously presented) A method for the treatment and/or prevention

of metabolic syndrome, whereby a pharmaceutically and pharmacologically effective amount of **an angiotensin II type 1 receptor antagonist alone or in combination with a metabolically neutral antihypertensive substance** is administered to a subject in need of such treatment or prevention. (emphasis added)

The context of the claim must be taken into account. As can be seen from the plain reading of the claim, an angiotensin II type 1 receptor antagonist is administered to a subject either: 1) alone, or 2) in combination with a metabolically neutral antihypertensive substance (as amended herein, a calcium channel antagonist). The term “alone”, thus, refers to the active ingredient – either 1) angiotensin II type 1 receptor antagonist as the active ingredient or 2) angiotensin II type 1 receptor antagonist in combination with another active ingredient (as amended herein, a calcium channel antagonist). The term “alone” in no way means that the angiotensin II type 1 receptor antagonist is administered without other non-active ingredient substances (i.e., carriers, diluents, etc).

Persons of ordinary skill would have no difficulty in determining whether a particular composition being administered comprised angiotensin II type 1 receptor antagonist alone, or rather, comprised angiotensin II type 1 receptor antagonist in combination with a metabolically neutral antihypertensive substance (or, as amended herein, a calcium channel antagonist). Thus, the claims are definite within the meaning of §112. *In re Mercier*, 185 U.S.P.Q. 774 (C.C.P.A. 1975) (claims sufficiently define an invention so long as one skilled in the art can determine what subject matter is or is not within the scope of the claims). Therefore, claims 11-13 and 17-20 are clear and definite. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, second paragraph be withdrawn.

## V. Conclusion

In view of the foregoing, Applicants respectfully submit that the claims are in condition for allowance. An early notice of the same is earnestly solicited. The Office is invited to contact Applicants' undersigned representative at (610) 640-7859 if there are any questions regarding Applicants' claimed invention.

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**PATENT**

The Commissioner is hereby authorized to debit any underpayment of fee due or credit any overpayment to Deposit Account No. 50-0436.

Respectfully submitted,

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